

Buchanan Ingersoll PC

ATTORNEYS

Edward John Allera
(202) 452-7985
alleraej@bipc.com

1100 K Street, N.W. Suite 300
Washington, DC 20006-3807

T 202 452 7900
F 202 452 7989

www.buchananingersoll.com

0322 '06 FEB -2 P 124

February 2, 2006

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

**Re: Docket No. 2005P-0383 - Article in Support of the Citizen Petition filed by
Savient Pharmaceuticals, Inc.**

Dear Sir or Madam:

The enclosed article is submitted on behalf of Savient Pharmaceuticals Inc. ("Savient") in support of its September 2005 Citizen Petition.

The article, written in part by a Food and Drug Administration ("FDA") pharmacologist, confirms the serious risk of administering oxandrolone in the geriatric population without adequate dosing information. Specifically, the article discusses the risks of excessive bleeding when administering oxandrolone to a patients taking warfarin. The article concludes that "any increased use of oxandrolone in the geriatric population enhances the potential for a clinically significant drug interaction resulting in bleeding."

The article describes the case of a 93-year-old woman on long-term warfarin sodium treatment who received oxandrolone to facilitate weight gain. After two weeks of taking oxandrolone in combination with warfarin, the patient's prothrombin time had increased over 400% – from 15.6 seconds to over 65 seconds. The article stated that a similar drug interaction causing excessive anti-coagulation also occurred in a 69-year-old patient taking warfarin and topical testosterone, which is chemically related to oxandrolone. In this case, the combination required a warfarin dose reduction of 25% to maintain therapeutic prothrombin time.

As Savient argued in its petition, any generic oxandrolone product would be less safe than Oxandrin[®] because a generic oxandrolone product could not include Savient's geriatric dosing information on its label.¹ The risk of a patient receiving an incorrect dosage of oxandrolone is especially grave in the geriatric population given the nature of oxandrolone's adverse drug interaction with warfarin and the widespread use of warfarin in the elderly. This

¹ Citizen Petition, Docket No. 2005P-0383, Sep. 19, 2005, at 13-18.

2005P-0383

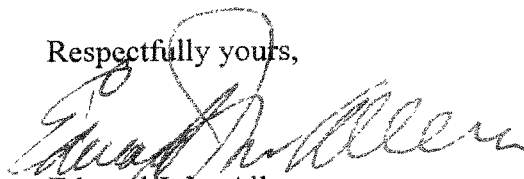
SUP 1

February 2, 2006

Page - 2 -

risk provides further evidence that no generic oxandrolone product can be safely used without Savient's geriatric dosing information and thus FDA is precluded from approving any generic versions of oxandrolone until Savient's exclusivity on its geriatric dosing information has expired.

Respectfully yours,

A handwritten signature in dark ink, appearing to read "Edward John Allera". The signature is fluid and cursive, with a large, stylized initial "E".

Edward John Allera

William A. Garvin